

REMARKS

Claims 24 and 26-48 are still pending in this application. Applicant respectfully requests reconsideration of this application which is being presented without any amendment to the claims.

In the Office Action, the Examiner indicated that claims 27-34 and 47 would be allowable if they are rewritten in independent form and that claims 35-43 are allowable over the prior art. Applicant gratefully acknowledges the Examiner's indication of allowable subject matter.

The Examiner objected to the drawings because a gas transfer system does not have a reference numeral. Applicant has amended the drawing and the corresponding specification by adding the reference numeral 1.

The Examiner rejected claims 24, 26, 44-46 under 35 U.S.C. Section 102(b) as being anticipated by or in the alternative under 35 U.S.C. Section 103(a) as being obvious over Teirstein (U.S. Patent No. 5,779,666). Applicant requests reconsideration of the rejection.

As discussed in Applicant's previous response, an important feature of Applicants' invention is the manner in which the two one-way valves 19 and 18 operate to assure proper and safe operation of the system. When the pump 13 is drawing in contrast medium from the bag 11, it is important that the valve 19 automatically open and the valve 18 automatically close. The contrast medium will flow into the pump and nothing will flow upstream from the connecting tube 22. Thus nothing will flow upstream from the vascular system to which the apparatus is connected.

It is further important that when the pump 13 delivers the contrast medium from the pump to the vascular system, that the valve 19 automatically close. The contrast medium is not returned to the bag 11 and the valve 18 will automatically open so that the contrast medium can be delivered through the connecting tubular member 22 to the vascular system.

As persons of ordinary skill in the art will appreciate, it is particularly advantageous that these two valves 19 and 18 automatically open and close in response to the differential pressures to which they are subjected so that this operation proceeds with

assurance and with safety. Therefore, no error can be made by a human operator in opening or closing any valves. In order for this objective to be met and the functions that are provided by these valves 19 and 18 to occur, there should be no ports other than the three ports 24, 25 and 27 through which the contrast medium passes.

If there are any other ports in the manifold defined by the inlet port 24 (controlled by valve 19), the outlet port 27 (controlled by valve 18) and the inlet-outlet port 25 (connected to the pump 13) an automatic, safe and assured system would not function properly.

All independent claims recite this automatic valve feature. For example, claim 24 recites:

the delivering step including: suctioning at said first inlet-outlet port by the pump **to cause said first one-way valve to automatically open**, allowing flow of contrast medium from said bag into the pump, **and to cause said second one-way valve to automatically close**, preventing fluid flow upstream from said connecting tubular member into the pump, and

exerting positive pressure at said first inlet-outlet port from the pump **to cause said second one-way valve to automatically open**, allowing fluid flow from said pump into said tubular member, **and to cause said first one-way valve to automatically close**, preventing upstream fluid flow to the source.

The Examiner concedes that Teirstein does not make it clear that its valves could be automatically responsive to low and high pressures. However, because Teirstein suggests that the manifold can be replaced by a check valve or multi-ported ball valve, the Examiner makes a logical leap that these valves can be designed to operate exactly as the claimed invention. Applicant respectfully disagrees with the Examiner's logical leap because Teirstein teaches away from the claimed invention as discussed below.

Teirstein is not interested in a fool proof closed system of delivering contrast media. Rather, Teirstein is only interested in reusing the bag filled with contrast media by placing a deformable holding chamber 14 between the bag 12 and the manifold 16. This is the reason why Teirstein shows in all figures extra ports 44 and 46 and clearly states in col. 4, lines 57-59, that the manifold 16 typically has other extra valves (ports).

Accordingly, even if the manifold 16 is replaced with a check valve or a multi-ported valve, Teirstein clearly suggests that such a valve would also have those extra ports.

This means that when the syringe is pulled to suck the contrast media from the holding chamber 14, the low pressure inside the manifold 16 in the form of a multi-ported ball valve or a check valve will cause the one-way valves at ports 44 and 46 to open which will suck in air or whatever source is connected to those valves. In other words, Teirstein allows “fluid flow upstream” from whatever source is connected to the valves 44-46 which would contaminate the closed system of the present invention. Accordingly, the suggestion of such additional ports in the valve teaches away from the claimed invention.

Moreover, even if the Examiner’s logical leap is correct and that a closed multi-ported valve with only the three ports (through which the contrast medium passes) is employed, it still does not teach all elements of the claimed invention.

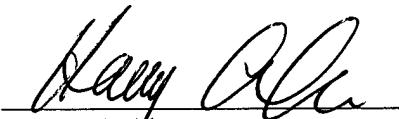
Claim 24 requires a closed system where the drawing step includes “**to cause said first one-way valve to automatically open**, allowing flow of contrast medium from said bag into the pump, **and to cause said second one-way valve to automatically close**, preventing fluid flow upstream from said connecting tubular member into the pump”. Further, Claim 24 requires a delivering step including “**to cause said second one-way valve to automatically open**, allowing fluid flow from said pump into said tubular member, **and to cause said first one-way valve to automatically close**, preventing upstream fluid flow to the source” (emphasis added).

By contrast, Teirstein neither teaches nor suggests such a precisely defined interaction between the two valves during the drawing and delivering step. In the Office Action, the Examiner on page 4 and on page 5 (response to arguments) appears to suggest that such a precise interaction between the two valves is well known. The Examiner also states that the “check and ball valves work automatically as clearly disclosed in Applicant’s specification”. Applicant respectfully submits that the present specification is not prior art and the Examiner cannot rely on Applicant’s own specification as prior art. The Examiner is impermissibly relying on his own knowledge that such a precise interaction between the two one-way valves as claimed in claim 24 is well known

because such claimed interaction is not taught at all in Teirstein and because the obviousness rejection of claim 24 was accompanied by only a single reference. Under MPEP Section 2144.03, Applicant respectfully requests the Examiner to produce a prior art reference that supports his view that such precise interaction of the two one-way valves is well-known. If the Examiner cannot produce such a reference, Applicant respectfully requests the Examiner to withdraw the rejection of claim 24, 26, 44-46 and 48.

Based upon the above amendments and remarks, applicants respectfully request reconsideration of this application and its early allowance. Should the Examiner feel that a telephone conference with applicants' attorney would expedite prosecution of this application, the Examiner is urged to contact him at the number indicated below.

Respectfully submitted,

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